

## Food and Drug Administration, HHS

## § 524.1200a

milligram (mg) gentamicin base, mometasone furoate monohydrate equivalent to 1-mg mometasone, and 10 mg clotrimazole, USP.

(b) *Sponsor*. See No. 000061 in § 510.6(c) of this chapter.

(c) *Conditions of use—Dogs—*(1) *Amount*. For dogs weighing less than 30 pounds (lb), instill 4 drops from the 5- and 30-gram (g) bottle into the ear canal (2 drops from the 215-g bottle) or, for dogs weighing 30 lb or more, instill 8 drops from the 5- and 30-g bottle into the ear canal (4 drops from the 215-g bottle), twice daily for 7 days.

(2) *Indications for use*. For the treatment of otitis externa associated with yeast (*Malassezia pachydermatis*) and/or bacteria susceptible to gentamicin in dogs.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[66 FR 712, Jan. 4, 2001]

### § 524.1193 Ivermectin pour-on.

(a) *Specifications*. Each milliliter (mL) of solution contains 5 milligrams of ivermectin.

(b) *Sponsors*. See Nos. 050604, 051259, 051311, and 059130 in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(c) *Related tolerances*. See § 556.344 of this chapter.

(d) *Special considerations*. See § 500.25 of this chapter.

(e) *Conditions of use*. (1) *Amount*. One mL per 22 pounds of body weight.

(2) *Indications for use in cattle*. It is used topically for the treatment and control of: Gastrointestinal roundworms (adults and fourth-stage larvae) *Ostertagia ostertagi* (including inhibited stage), *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia* spp., *Oesophagostomum radiatum*; (adults) *O. venulosum*, *Strongyloides papillosus*, *Trichuris* spp.; lungworms (adults and fourth-stage larvae) *Dictyocaulus viviparus*; cattle grubs (parasitic stages) *Hypoderma bovis*, *H. lineatum*; mites *Chorioptes bovis*, *Sarcoptes scabiei* var. *bovis*; lice *Linognathus vituli*, *Haematopinus eurysternus*, *Damalinea bovis*, *Solenoptes capillatus*; horn flies *Haematobia irritans*. It is also used to control infections of gastrointestinal roundworms

*O. ostertagi*, *O. radiatum*, *H. placei*, *T. axei*, *Cooperia punctata*, and *C. oncophora* for 14 days after treatment.

(3) *Limitations*. Do not treat cattle within 48 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

[55 FR 50551, Dec. 7, 1990, as amended at 62 FR 38908, July 21, 1997; 62 FR 63271, Nov. 28, 1997; 63 FR 44385, Aug. 19, 1998; 66 FR 13236, Mar. 5, 2001; 66 FR 63165, Dec. 5, 2001]

### § 524.1195 Ivermectin otic suspension.

(a) *Specifications*. Each tube contains 0.5 milliliter (mL) of a 0.01 percent suspension of ivermectin.

(b) *Sponsor*. See No. 065274 in § 510.600(c) of this chapter.

(c) *Conditions of use—*(1) *Amount*. Administer the contents of one 0.5-mL tube topically into each external ear canal.

(2) *Indications for use*. For the treatment of adult ear mite (*Otodectes cynotis*) infestations in cats and kittens 4 weeks of age and older. Effectiveness against eggs and immature stages has not been proven.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[66 FR 7578, Jan. 24, 2001]

### § 524.1200 Kanamycin ophthalmic and topical dosage forms.

#### § 524.1200a Kanamycin ophthalmic ointment.

(a) *Specifications*. The drug, which is in a suitable and harmless ointment base, contains 3.5 milligrams of kanamycin activity (as the sulfate) per gram of ointment.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*. It is indicated for use in dogs in various eye infections due to kanamycin sensitive bacteria. It is used treating conditions such as conjunctivitis, blepharitis, dacryocystitis, keratitis, and corneal ulcerations and as a prophylactic in traumatic conditions, removal of foreign bodies, and intraocular surgery. Apply a thin film to the affected eye three or four times daily or more frequently if deemed advisable. Treatment should be continued